

Innovation In Ophthalmology

**Corporate Overview** *June 2020* 



### **Disclaimers and Notices**

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties, including statements regarding INVELTYS®, for post-operative inflammation and pain following ocular surgery, including progress of commercial launch, the Company's lead product candidate, EYSUVIS<sup>TM</sup>, for the short-term relief of the signs and symptoms of dry eye disease, including expectations regarding timing of FDA review of the NDA and potential launch by year-end 2020, the market for EYSUVIS, including the potential for EYSUVIS to be suitable for the vast majority of patients with dry eye disease, the Company's plan to expand its commercial sales force and the Company's expectations regarding its use of cash, cash runway and projected revenues. All statements, other than statements of historical facts, contained in this presentation, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forwardlooking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of various risks and uncertainties including, but not limited to: the impact of extra ordinary external events, such as the current pandemic health event resulting from the novel coronavirus (COVID-19), and their collateral consequences, including disruption of the activities of our sales force and the market for INVELTYS and any delay in timing of regulatory review of the NDA for EYSUVIS; whether the Company will be able to success fully implement its commercialization plans for INVELTYS and EYSUVIS, if approved; whether the market opportunity for INVELTYS and EYSUVIS is consistent with the Company's expectations and market research; whether any additional clinical trials will be initiated or required for EYSUVIS prior to approval of the NDA, or at all, and whether the NDA for EYSUVIS will be approved on the timeline expected or at all; the Company's ability execute on the commercial launch of EYSUVIS, if and when approved, on the timeline expected, or at all; whether the Company will be able to generate its projected net product revenue on the timeline expected, or at all; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of INVELTYS and the Company's product candidates, including EYSUVIS; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission.

All information in this presentation is as of June 9, 2020 and should not be considered current after such date. We do not as sume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.



### **Key Highlights**



- Proprietary AMPPLIFY® drug delivery technology to enhance delivery to target tissues of the eye
- IP protection for AMPPLIFY technology and products through 2033



(KPI-121 0.25%) for Dry Eye Disease

- Potential to become the preferred first-line prescription therapy for the short-term treatment of dry eye disease
- STRIDE 3 trial successfully achieved primary and key secondary endpoints
- STRIDE 3 replicates the successful results of the prior clinical trials and addresses CRL recommendation for an additional positive trial
- NDA accepted for review by FDA; PDUFA goal date of Oct 30, 2020 and potential U.S. launch in 2H 2020



- Approved by FDA in August 2018 with U.S. launch in January 2019
- FIRST & ONLY post-surgical steroid with class-leading combination of powerful efficacy, a safety profile comparable to vehicle, and BID dosing

#### **Corporate Highlights**

- Cash and cash equivalents of \$196.5 million as of March 31, 2020
- Raised \$146.9M in gross proceeds from Q1 2020 sales of common stock, including follow-on offering in March 2020 and sales under our "at-the-market" program
- Existing cash resources expected to fund operations into at least the second quarter of 2022





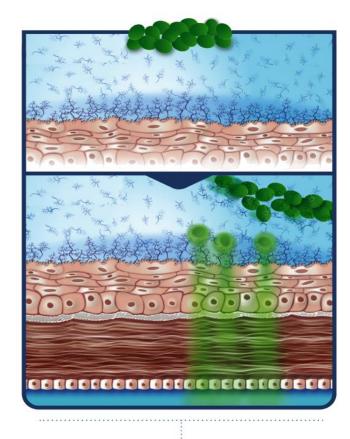
## Mucus is an Innate Defense Mechanism That Can Impair Drug Delivery

- Heterogeneous mesh of mucin fibers present in tear film and other protective coatings in the body
- Mucus binds drugs and other particulate matter to facilitate elimination via tear turnover:
  - 1. Small particles (<500 nm) penetrate into mucus pores and are bound by charged macromolecules inside the pores
  - 2. Large particles (larger than mucus pores) are bound to the surface of mucus

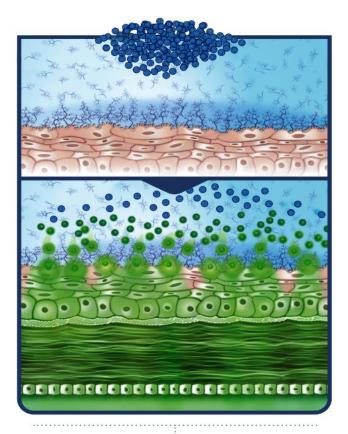
Sources: Olmstead et al. Biophys J 2001; Sigurdsson, Kirch & LehrInt J Pharm 2013

AMPPLIFY utilizes nanoparticles (~300 nm on average) engineered via surface modification to penetrate through mucus pores to the ocular surface without being bound up and eliminated by the tear film

# AMPPLIFY Technology Increases LE Penetration to Corneal and Aqueous Humor By More Than 3x



Traditional suspension eye drops adhere to mucins and can be rapidly cleared through blinking



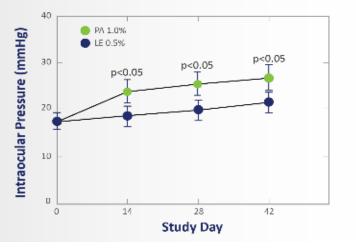
Drug particles formulated with **AMPPLIFY™ Drug Delivery Technology** are designed to enhance penetration through the mucus barrier and deliver increased concentrations of drug to the target ocular tissues



# Loteprednol Etabonate (LE) is a Potent Steroid With Improved Safety Characteristics

- Ester steroid differs from traditional ketone-based steroids by its metabolism to inactive metabolites
- 4.3X greater glucocorticoid receptor (GR) binding affinity versus dexamethasone
- Therapeutic effect followed by predictable single-step de-esterification to inactive carboxylic acid metabolites
- Enhanced clinical safety relative to current ketone steroids
- Clinical efficacy/potency limited by poor penetration into ocular tissues

## Effect on IOP in steroid responsive patients (LE vs prednisolone acetate (PA))



#### Loteprednol etabonate (active)

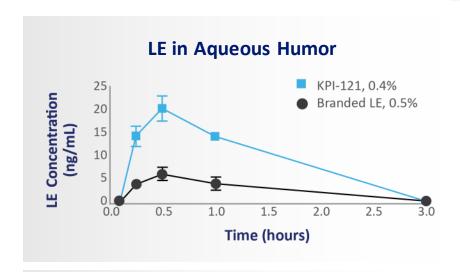
Loteprednol etabonte

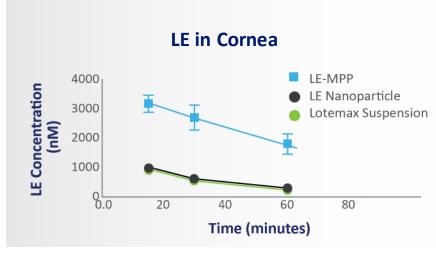
#### **Inactive carboxylic acid metabolites**



### Leveraging LE MPP to Enhance Delivery to Target Ocular Tissues

- KPI-121: MPP loteprednol etabonate (LE)
  - INVELTYS® (KPI-121 1%): Approved Product for Post-Surgical Pain & Inflammation with BID Dosing
  - EYSUVIS™ (KPI-121 0.25%): Product Candidate for Dry Eye Disease
- AMPPLIFY technology increases LE penetration to corneal and aqueous humor by more than 3x
- Aqueous Humor concentrations mediate resolution of inflammation following ocular surgery
- Corneal deposition is a key driver for Dry Eye efficacy and resolution of pain following ocular surgery











INVELTYS: FIRST AND ONLY Approved BID Post-Surgical Steroid

## INVELTYS: The First & Only Post-Surgical Steroid Approved With BID Dosing

- INVELTYS launched in January 2019
- WAC price of \$269.53/Rx
- Dedicated specialty ophthalmology sales force and account director team
- Commercial and Medicare co-pay assistance programs for eligible patients



INVELTYS is indicated to treat inflammation and pain following **ALL** ocular surgeries

INVELTYS is the *FIRST AND ONLY* post-surgical steroid shown to be effective and approved with BID dosing

INVELTYS has an excellent safety and tolerability profile, with IOP results similar to placebo

INVELTYS utilizes AMPPLIFY nanoparticle technology that delivers more loteprednol directly to the target ocular tissue while maintaining an excellent safety profile



## **Key Aspects of INVELTYS**

#### **Indication Statement Covers All Ocular Surgery:**

"INVELTYS is a corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery."

#### First FDA Approved Ocular Steroid With BID Dosing:

"Instill one to two drops of INVELTYS into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period."

#### **Low Rates of Adverse Events:**

"The most common adverse drug reactions in the clinical trials with INVELTYS were eye pain and posterior capsular opacification, both reported in 1% of patients. These reactions may have been the consequence of the surgical procedure."

Intraocular Pressure Results Similar to Vehicle

Packaged Product Will Have 24 Months of Expiry Dating at Controlled Room Temperature

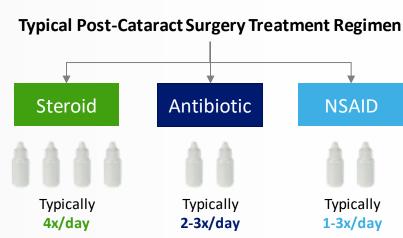
**No Additional Post-Approval Commitments** 



# Steroids are Standard of Care for Treating Inflammation and Pain Following Ocular Surgery

- Eye care professionals (ECPs) report prescribing steroids in greater than 90% of cataract, glaucoma and refractive surgeries\*
- Current ocular steroids are approved for TID or QID dosing, which can lead to issues with adherence to the steroid regimen
- An effective and safe topical steroid with BID dosing would be a significant benefit in the management of patients following ocular surgery

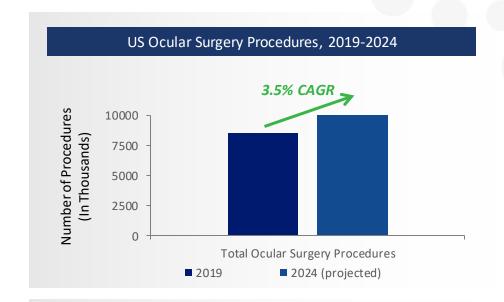


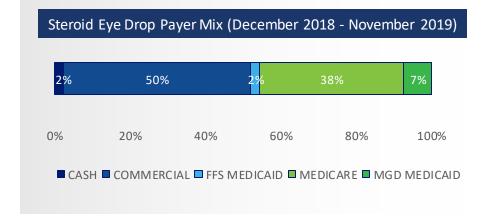




## The Ocular Surgery Market is Large and Expected to Continue to Grow

- ~8.6M ocular surgery procedures in 2019 in the U.S.;
   projected to grow at a CAGR of 3.5% through 2024
- Branded products account for ~23% of prescriptions and ~52% of gross sales
- At current branded prices, the market is estimated to be valued at ~\$2.1B
- Approximately 6,500 Eye Care Professionals (ECPs) account for 80% of the target surgical business
- Steroid market payer mix is ~52% Commercial/Cash and ~38% Medicare

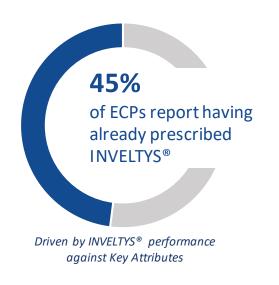


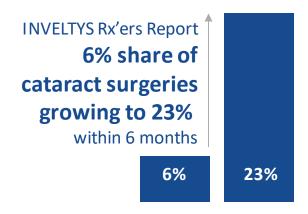




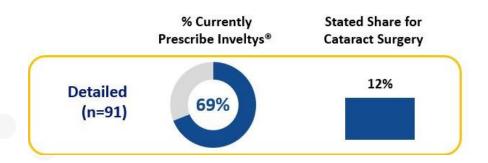
## INVELTYS has Achieved Strong Acceptance with Target ECP Audience

#### **INVELTYS** has achieved strong acceptance across the entire ECP audience





#### ECPs who hear the INVELTYS story are very likely to prescribe

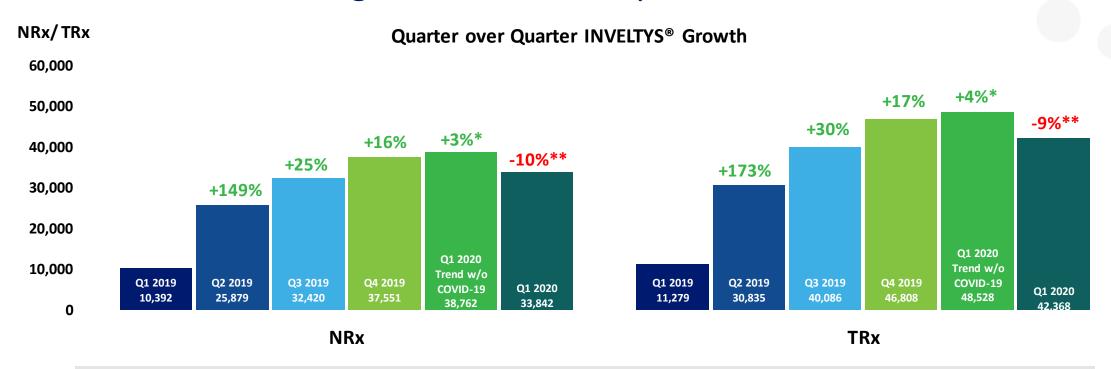


Of the remaining 31%, **57% report they intend to prescribe INVELTYS**within the next 6 months

They would achieve a **7% market share** of cataract surgeries in 6 months



## INVELTYS® Was Showing Continued Prescription Growth Prior to COVID-19



- >175,000 TRxs since launch
- INVELTYS TRxs were trending to grow 4% quarter over quarter (Jan/Feb) prior to COVID-19 impact
  - During this time the overall ocular steroid market was trending down ~2% and branded steroid eye drops down 14.1%
- Branded NRx market share of 18.6% for called on physicians pre-COVID-19



<sup>\*</sup>Trend based on Symphony reported through 2/28 and trended through end of quarter

<sup>\*\*</sup>Data Based on reported Symphony PHAST Pack Units



EYSUVIS<sup>TM</sup> (Loteprednol Etabonate Ophthalmic Suspension) 0.25% for Dry Eye Disease

# NDA Accepted for Review by FDA; PDUFA Goal Date of Oct 30, 2020 and Potential US Launch in 2H 2020

STRIDE 3
Primary & Key
Secondary
Endpoints
Achieved

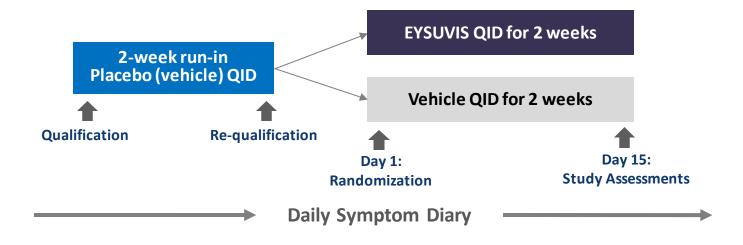
- ✓ Statistical significance for primary endpoint of ODS in the overall ITT population (p=0.0002)
- ✓ Statistical significance for primary endpoint of ODS in patients with higher baseline (p=0.0007)
- ✓ Statistical significance achieved for prespecified key secondary endpoints
  - Conjunctival hyperemia at day 15 in the ITT population (p<0.0001)</li>
  - ODS at day 8 in the ITT population (p=0.0282)
- ✓ EYSUVIS was well tolerated, with AE and IOP profile similar to vehicle

EYSUVIS
Program
Next Steps

- ✓ STRIDE 3 replicates the successful results of the prior clinical trials
- ✓ Statistical significance achieved for sign endpoint in STRIDE 1, STRIDE 2 and STRIDE 3
- ✓ Statistical significance for both symptom endpoints in STRIDE 1 and STRIDE 3
- ✓ Significant benefit observed for corneal staining in STRIDE 2 and STRIDE 3
- ✓ EYSUVIS was well tolerated in all trials; AEs and IOP elevation rates similar to vehicle
- ✓ STRIDE 3 results address CRL recommendation for an additional positive trial



### STRIDE 3 Trial Design



#### **Study Population**

901 patients with diagnosed dry eye disease

#### **Key Inclusion Criteria:**

- Investigator rated bulbar conjunctival hyperemia before and after vehicle run-in
- Ocular discomfort visual analog score before and after vehicle run-in
- Corneal fluorescein staining score before and after vehicle run-in

#### **Primary Endpoints in STRIDE 3:**

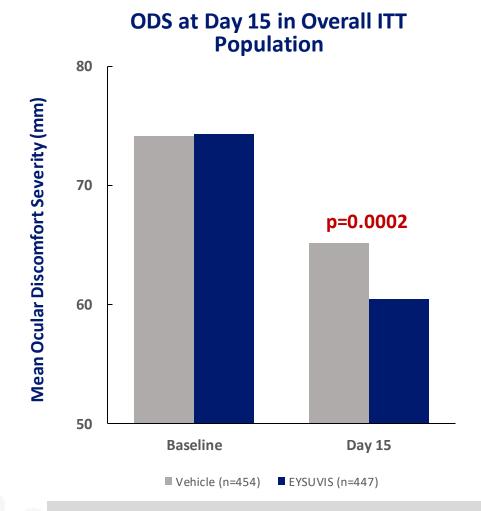
- Change from baseline in Ocular Discomfort Severity
   (ODS) score at Day 15 in overall ITT population
- Change from baseline in ODS score at Day 15 in ITT patients with more severe baseline discomfort (≥68 mm)

#### **Key Secondary Endpoints:**

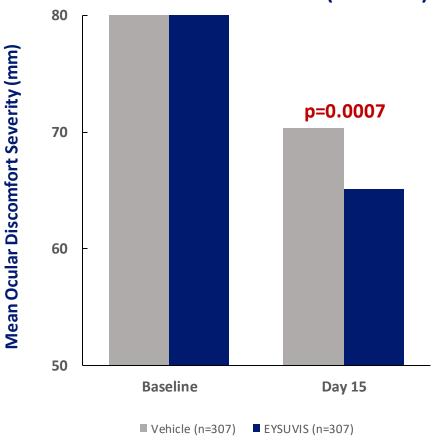
- Conjunctival hyperemia at day 15 in ITT population
- ODS at Day 8 in ITT population



### Statistical Significance Achieved For Both Prespecified Primary Endpoints





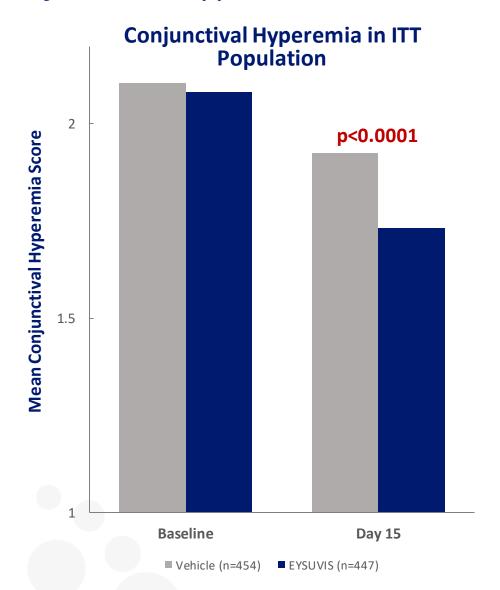




Results replicate primary symptom endpoint results from STRIDE 1



# Statistical Significance Achieved For Key Secondary Endpoint Of Conjunctival Hyperemia



Results replicate primary sign endpoint results from STRIDE 1 and STRIDE 2



# EYSUVIS Was Well Tolerated in STRIDE 3, With Adverse Events and Intraocular Pressure Increases Similar to Vehicle

#### Adverse Events Reported by >1% of Patients

	EYSUVIS	Vehicle
Instillation site pain	13/449 (2.9%)	7/452 (1.5%)

## Number of Patients with IOP Increase > 5 mmHg Leading to IOP ≥ 21 (Study Eye)

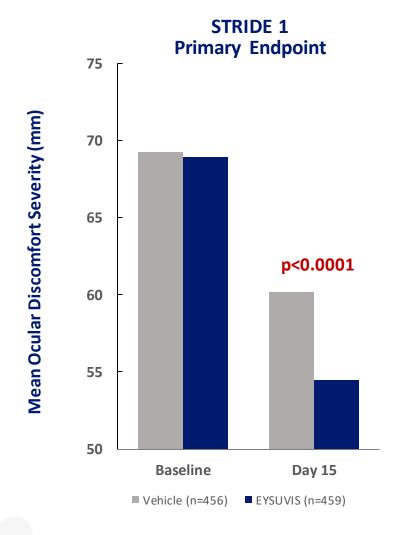
EYSUVIS	Vehicle
0/449	0/452
(0.0%)	(0.0%)

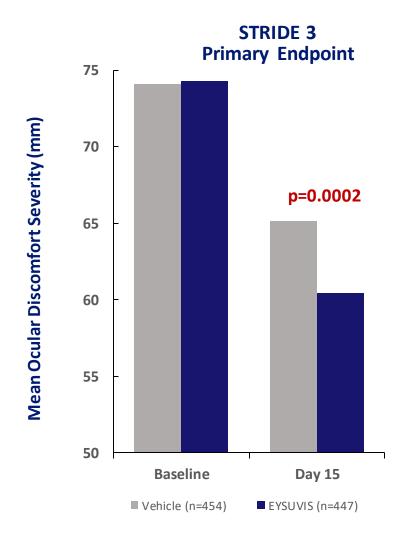
## Number of Patients with IOP Increase > 10 mmHg (Study Eye)

EYSUVIS	Vehicle
0/449	0/452
(0.0%)	(0.0%)



# Consistent Improvement in Primary Symptom Endpoint in Overall ITT Population in STRIDE 1 and STRIDE 3

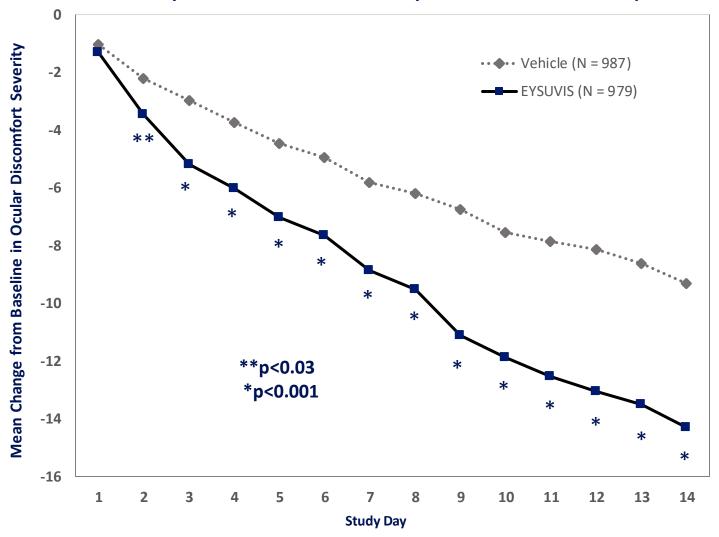






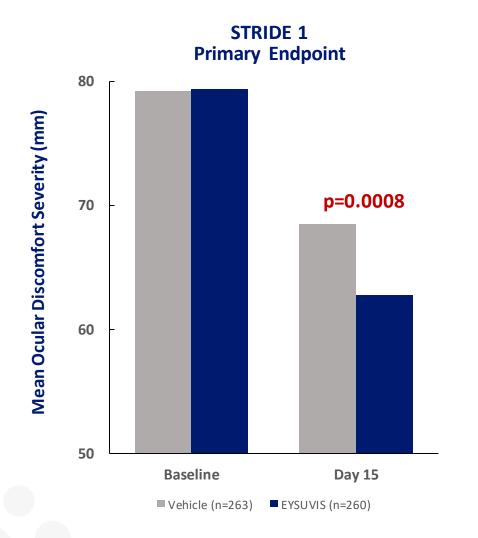
## Rapid and Sustained Improvement Starting Day 2

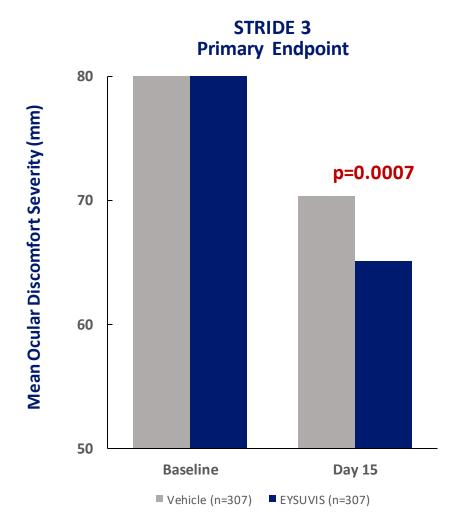
#### **Pooled Daily Ocular Discomfort Severity Scores in Overall ITT Population**





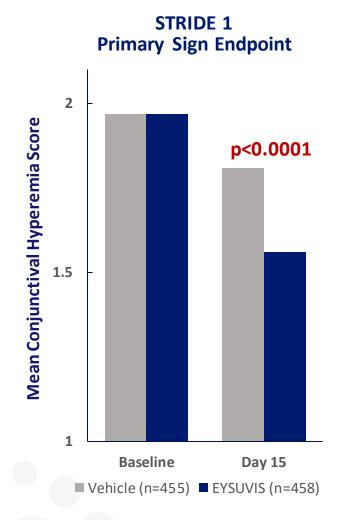
# Consistent Improvement in Primary Symptom Endpoint in ITT Patients with More Severe Baseline Discomfort in STRIDE 1 and STRIDE 3

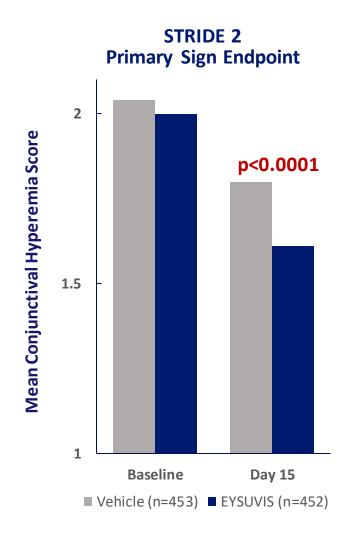


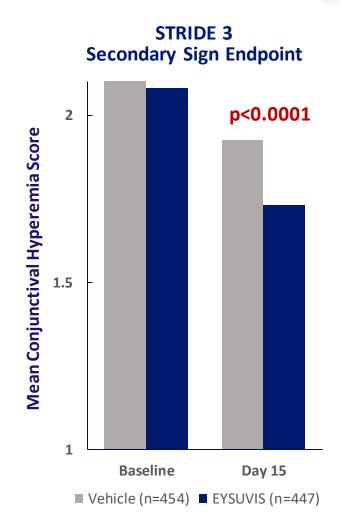




# Consistent Improvement in Sign Endpoint in STRIDE 1, STRIDE 2 and STRIDE 3 Trials

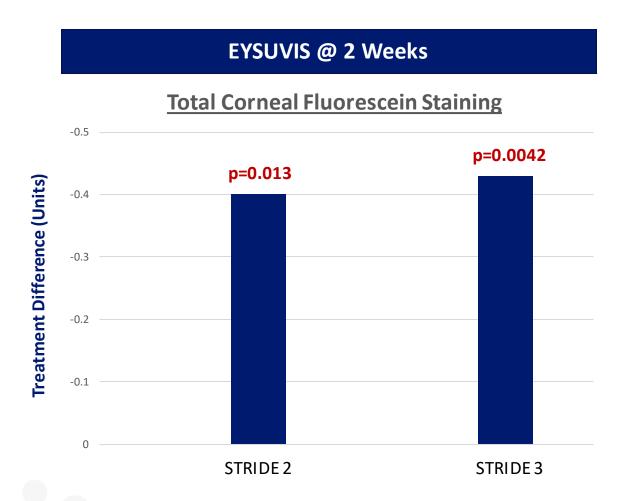








## EYSUVIS Corneal Fluorescein Staining Improvement at 2 Weeks



- Inflammation and corneal damage are hallmark signs in Dry Eye Disease
- Significant benefit in total corneal fluorescein staining observed at 2 weeks in STRIDE 2 and STRIDE 3
- Strong data on conjunctival hyperemia and corneal staining demonstrates a rapid and robust effect on inflammation



# EYSUVIS Was Well Tolerated Across All Three Phase 3 Trials, With an IOP Profile Similar to Vehicle

#### Adverse Events Reported by >1% of Patients

	EYSUVIS	Vehicle
Instillation site pain	67/1360 (4.9%)	55/1361 (4.0%)

## Number of Patients with IOP Increase > 5 mmHg Leading to IOP ≥ 21 (Study Eye)

EYSUVIS	Vehicle
7/1360	2/1361
(0.5%)	(0.15%)

## Number of Patients with IOP Increase > 10 mmHg (Study Eye)

EYSUVIS	Vehicle
2/1360	0/1361
(0.15%)	(0.0%)



### Anticipated 2020 Key EYSUVIS Catalysts

1Q 2020
STRIDE 3 Topline
Results

2Q 2920

Resubrait NDA

(Class esubmission; 6-month review)

Oct 30, 2020

Potential FDA Approval

2H 2020

Potential Launch





## Majority of DED Patients Suffer From Flares and Not Continual Symptoms

#### **Dry Eye Disease (DED) Flare Definition<sup>1</sup>**:

Rapid-onset, inflammation-driven response to a variety of triggers that typically cannot be adequately managed with patient's ongoing maintenance therapy (e.g., artificial tears, chronic Rx therapies)

~80-90%

of all DED patients report they suffer from flares 2,3

of patients on artificial tears report they suffer from flares<sup>2</sup>

of patients on Restasis or Xiidra report they suffer from flares<sup>2</sup>

<sup>3.</sup> Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third



<sup>1.</sup> ASCRS EyeWorld. https://www.eyeworld.org/download/file/fid/453. Published May 2019. Accessed May 24, 2019. 2. Based on a survey of 297 patients commissioned by Kala and performed by a third party.

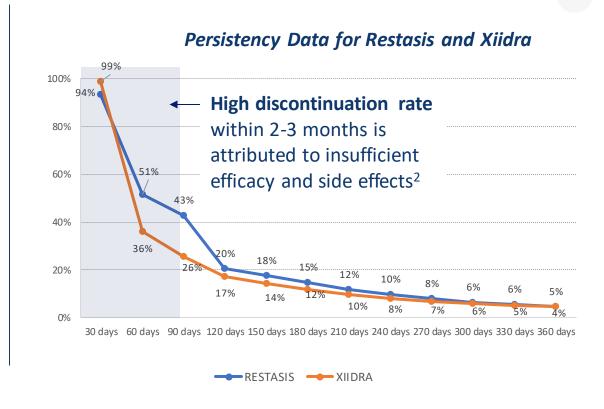
## High Discontinuation Rates for Current Prescription DED Treatment Options

#### **Current Rx DED Therapies**

Onset of action (weeks to months) not optimal for treating DED flares

Insufficient efficacy and side effects main reasons cited by patients for discontinuing current prescription therapies<sup>1</sup>

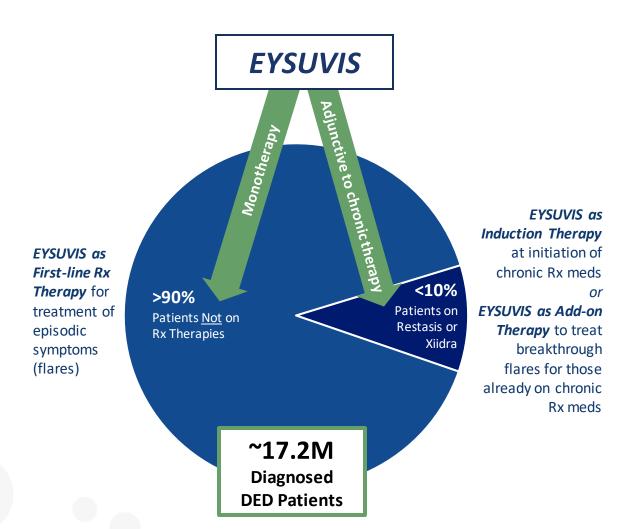
Intended to be taken on a daily chronic schedule



- Despite only ~1M patients on Rx therapies, 2018 sales of Restasis and Xiidra were approximately \$1.2B and \$383M
- In May 2019, Novartis acquired Xiidra for \$3.4B in cash and a total consideration of up to \$5.3B



### EYSUVIS May Be Suitable for the Vast Majority of Patients with Dry Eye Disease



Patients with DED are in the Office Seeking Treatment

2-3x

Patients with DED are in the Eye Care Professional (ECP) office an average of 2-3 times per year

42%

of annual ECP office visits are for DED flares



## EYSUVIS is Poised to Answer Unmet Needs in DED

- **Broad anti-inflammatory activity** addresses key driver of DED
- In clinical trials **EYSUVIS** provided **rapid onset of relief** of signs and symptoms of DED
- In clinical trials **EYSUVIS** was **well tolerated** with low incidence of IOP elevations (similar to vehicle)
- If approved, EYSUVIS will be first ocular steroid to have a dry eye disease indication

#### Eye Care Professionals (ECPs) prefer an on-label steroid for DED:1

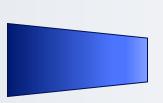
- Off-label steroids have varied safety profiles
- Risk of IOP elevation when prescribing steroids off-label
- Patient comfort having DED indication in the Package Insert
- Efficacy and safety vetted by the FDA

Over 95% of ECPs are interested in the availability of a steroid with a DED indication<sup>1</sup>

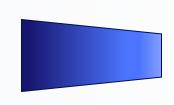


# Currently Only 2.9% of the 17.2M Diagnosed DED Patients are Prescribed Off-Label Steroids

~1M
Steroid TRxs Each
Year For DED



~500K
DED Patients
With a Steroid Rx



Only 2.9%

DED Patients
On Off-Label Steroids

Today

## 10M Ocular Steroid TRxs Annually

- 71.3% for Ocular Surgery
- 10.8% for Allergic Conjunctivitis
- 10.2% for DED
- 7.7% for other indications

## Patients get an average of 2 Rxs/year

 1M TRxs /2 Rxs per patient year Of the **17.2M diagnosed DED patients** in the U.S.
Only 500K are receiving a steroid Rx



## There is Strong ECP & Patient Interest in the EYSUVIS Product Profile

## ECPs See Potential to Prescribe EYSUVIS for over half of their DED Patients\*



**53%** 

In patients managed primarily on OTC treatment experiencing flares

56%

In patients currently on Restasis experiencing flares

**52%** 

As induction therapy for patients starting Restasis or Xiidra

## DED Patients Expressed Strong Interest in EYSUVIS\*\*

#### **Patients indicated that:**

- 90% of patients interested in the profile and would ask their physicians for more information about EYSUVIS
- They would like a short-term flare treatment vs. a chronic medicine
- They want rapid and effective treatment



<sup>\*</sup>Based on a survey of 73 ophthalmologists commissioned by Kala and performed by a third party.

<sup>\*\*</sup>Based on a survey of 30 patients diagnosed with dry eye disease commissioned by Kala and performed by a third party.

### **EYSUVIS Market Potential**

**Patient Types** 

Currently
Diagnosed DED
Patients

% of DED Patients
ECPs Intend to Use
EYSUVIS

Total # Patients
Potentially on
EYSUVIS

Patients on OTCs/artificial tears ONLY

**16.2 Million Patients** 

**53%** 

8.6M Patients

Patients getting induction therapy before starting Restasis/Xiidra

**200K New Patients** 

**52%** 

104K Patients

Patients already on Restasis/Xiidra

800K Existing Patients

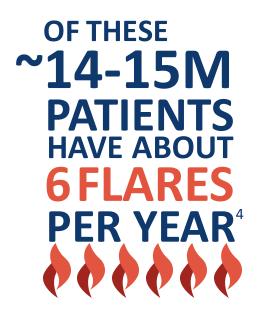
56%

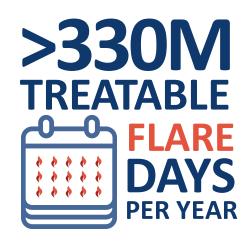
448K Patients ~9.2M
Potential
EYSUVIS
Patients



### Annual Total Addressable US Market for Dry Eye Disease Flares

80-90%
†††††††††
OF THE 17.2M
DIAGNOSED
DED PATIENTS
EXPERIENCE
FLARES 1-3





## >\$8B MARKET OPPORTUNITY



### Summary



(KPI-121 0.25%) for Dry Eye Disease

- Potential to become the preferred first-line prescription therapy for the short-term treatment of DED
- ~33M dry eye sufferers in U.S.
- >\$8B annual total addressable U.S. market opportunity for DED flares
- STRIDE 3 trial successfully achieved primary and key secondary endpoints
- STRIDE 3 replicates the successful results of the prior clinical trials and addresses CRL recommendation for an additional positive trial
- NDA accepted for review by FDA; PDUFA goal date of Oct 30, 2020
- Preparing for potential U.S. launch in 2H 2020 with existing Commercial infrastructure
- Plan to grow sales force to ~100-125 sales professionals to support launch of EYSUVIS and continue to promote INVELTYS



(loteprednol etabonate ophthalmic suspension) 1%

- First and ONLY BID ocular steroid
- ~8.6M ocular surgery procedures in the U.S. in 2019, projected to grow at 3.5% CAGR through 2024
- INVELTYS Achieved Strong Rx and Market Share Growth in 2019





**Thank You** 

